In re National Prescription Opiate Litigation: MDL 2804

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO MALLINCKRODT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Summary Sheet of Concise Issues Raised

Motion Name: Mallinckrodt's Motion for Partial Summary Judgment (Dkt. # 1778-1)

Concise Description of Issues: Mallinckrodt seeks partial summary judgment on the grounds that there is "no evidence" that: Mallinckrodt (a) promoted its generic products in a false and misleading manner; or (b) shipped a suspicious order to any customer or that Mallinckrodt's anti-diversion program was in any way deficient after 2012. As the evidence is sufficient to raise issues of fact on each of these points, summary judgment must be denied.

The record contains substantial evidence that Mallinckrodt promoted its generic products in a false and misleading manner, including to pharmacists and distributors through chronic pain brochures and pain "pocketcards" containing multiple misrepresentations about the safety and efficacy of chronic opioid use. Mallinckrodt also promoted opioid use overall through misleading unbranded marketing to physicians and patients. The dichotomy Mallinckrodt draws between "branded" and "generic" promotion is false. Mallinckrodt's misrepresentations were not specific to a particular opioid, generic or branded, but instead increased acceptance of widespread opioid use across the board—and, as a result, demand for generic opioids.

The record also contains substantial evidence that Mallinckrodt: (a) shipped massive volumes of opioids into Plaintiffs' jurisdictions and neighboring Ohio counties, including to pill mills and problem pharmacies; (b) relied on conflicted sales personnel—including a national account manager who compared opioid pills to Doritos chips—to help determine whether to ship suspicious orders; (c) shipped millions of opioids to wholesalers and downstream customers up until the time they were shut down by the DEA, (d) was aware that opioids shipped to Florida were being trafficked up I-75 to Ohio and other states, and (e) was aware of problems with abuse and diversion in Ohio yet continued with business as usual. In fact, Mallinckrodt is the only manufacturer Defendant to have been investigated by the DEA and that entered into an agreement admitting that certain aspects of its system to monitor and detect suspicious orders did not meet the standards outlined in guidance letters from the DEA. Even after 2012, Mallinckrodt continued to release suspicious orders based on flimsy representations from sales personnel, with the result that only a *de minimis* number of suspicious orders were stopped and reported to the DEA. Mallinckrodt also continued to ship significant volumes of opioids to distributors that were violating the law.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MALLINCKRODT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

July 31, 2019

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INTRODUCTION

Mallinckrodt has for years dominated the market for prescription opioids in the United States. Opioids are dangerous, highly addictive drugs, yet, for Mallinckrodt, they were products to be sold like any other. In January 2009—a year in which, according to the CDC, over 18,000 people died from opioid overdoses—Victor Borelli, one of Mallinckrodt's most highly compensated National Account Managers ("NAMs"), emailed one of his major wholesaler clients, Steve Cochrane from KeySource Medical, to let him know that 1200 bottles of Mallinckrodt oxycodone had been shipped. Cochrane replied:

"Keep'em comin'! Flyin' out of there. It's like people are addicted to these things or something. Oh, wait, people are . . ."

Mr. Borelli responded:

"Just like Doritos, keep eating. We'll make more."[1]

This exchange speaks volumes in explaining Mallinckrodt's dominance of the opioid market.

Mallinckrodt is a vertically integrated opioid manufacturer: it imports raw material, produces bulk active pharmaceutical ingredients, and manufactures finished dosage products, both generic and branded.[2] Between 1996 and 2017, Mallinckrodt was the leading manufacturer of generic opioid products, with over $18 billion in opioid sales.[3] Through its subsidiary SpecGx, Mallinckrodt manufactured over 28.8 billion opioid pills between 2006 and 2012, yielding a market share of 37.7%.[4] More than 135 million of these pills were supplied to Cuyahoga County, and more than 168 million to Summit County.[5] In addition to dominating the market for one of the most abused and diverted

[1] Ex. 1, MNK-T1_0000559532.

[2] Ex. 2, MNK-T1_0003076128 at p. 4 (Mallinckrodt diversion presentation identifying its areas of "expertise").

[3] *See* Ex. 3, Jan. 30, 2019 Mallinckrodt Response to Interrogatory ("MNK Rog Resp.") at No. 33 & Ex. E; *see also* Kevin Vordestrasse Dep. (12/05/18), Dkt. # 1985-8 at 123:24-123:7 (Mallinckrodt's 30(b)(6) witness testified that Mallinckrodt was either the number one or number two manufacturer with respect to generic opioids sold).

[4] Scott Higham, Sari Horwitz & Steven Rich, *76 billion opioid pills: Newly released federal data unmasks the epidemic*, WASH. POST, July 17, 2019, at A1.

[5] *Id.*

opioids—oxycodone—Mallinckrodt has for decades been one of the largest manufacturers in the nation of methadone, a drug commonly used to treat opioid addiction, and holds itself out as a leader in the field of addiction treatment. Mallinckrodt even offers Continuing Education courses with titles such as "Understanding Addiction: The Great Brain Robbery" and "The Addicted Brain: A Disease Perspective."[6]

Mallinckrodt LLC, SpecGX LLC, and Mallinckrodt plc (collectively, "Mallinckrodt") now move for partial summary judgment, claiming that the record lacks evidence of Mallinckrodt: (1) misleadingly promoting its generic products, (2) ever shipping a single suspicious order, and (3) having an inadequate anti-diversion program after 2012. ("MSJ" Dkt. # 1778-3) But in fact the evidence of wrongful Mallinckrodt conduct in connection with both its promotional and anti-diversion activities is substantial and demonstrates that Mallinckrodt played a pivotal role in the opioid epidemic, both nationally and in Plaintiffs' jurisdictions.

As discussed in Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication with Respect to Defendants' Duties Under the Controlled Substances Act (Dkt. # 1887 1) ("SOM-ACSA-Duties Brief") and Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Dkt. # 1924 1) ("CSA-Compliance Brief"),[7] at all times, Mallinckrodt was under statutory and regulatory duties to design and implement an effective system to protect against diversion. While Mallinckrodt has described itself as the model opioid manufacturer—better than the rest, and the darling of the DEA—in fact, Mallinckrodt's conduct was so egregious that it earned the unique distinction of being the first

[6] *See, e.g.*, Ex. 4, MNK-T1_0004367449 at 454 (listing seven educational programs "now available exclusively from and conducted by Covidien Mallinckrodt National Accounts Managers").

[7] Plaintiffs filed two separate motions regarding suspicious ordering monitoring, one (the "CSA-Duties" motion) addressing the scope of Defendants' duties and the other (the "CSA-Compliance" motion), setting forth the undisputed evidence that Defendants failed to comply with those duties.

opioid manufacturer sued by the United States Department of Justice based on the inadequacies in its anti-diversion programs. This resulted in a 2017 settlement in which Mallinckrodt paid a $35 million fine, agreed to implement specific anti-diversion steps, and admitted that for at least a four-year time period between 2008 and 2012, its system to monitor and detect suspicious orders did not meet the standards outlined by the DEA.[8] The Department of Justice described this as "the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances."[9]

In its Motion, Mallinckrodt goes so far as to say that it never promoted its generic products at all, MSJ. Dkt. # 1778-3 at 2, and that, other than a single order in 1998, it "never shipped any opioid products into Summit or Cuyahoga counties, at any time." *Id.* at 6. In other words, Mallinckrodt's arguments would require the Court to accept first that Mallinckrodt did not promote its generic products, yet coincidentally ended up with the largest market share in the nation; second that Mallinckrodt didn't "ship" its products to Ohio, yet it ended up supplying a quarter of Ohio's opioids by happenstance; and finally that Mallinckrodt had an "industry-leading" anti-diversion program, but nevertheless agreed in 2017 to pay a $35 million fine for violations and to substantially reform that program.

Plaintiffs have assembled ample evidence of Mallinckrodt's promotion of its generic products, its shipment of suspicious orders, and the continued deficiencies in its anti-diversion program after 2012. Mallinckrodt may at trial dispute the facts on each of these points, but it has not met the standard for summary judgment on any of Plaintiffs' claims.

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[8] *See* Ex. 5, MNK-T1_0000557100 at §I.4 (Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration, Mallinckrodt plc and Mallinckrodt LLC, July 10, 2017 ("AMOA")).

[9] Ex. 6, Press Release, U.S. Dep't of Justice (July 11, 2017), *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations.*

LEGAL STANDARD

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (*citing Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (*citing* same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (*citing Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

ARGUMENT

I. THE EVIDENCE IS SUFFICIENT TO RAISE A GENUINE ISSUE OF FACT THAT MALLINCKRODT PROMOTED ITS OPIOID PRODUCTS BY FALSELY REPRESENTING THE SAFETY AND EFFICACY OF OPIOIDS FOR CHRONIC PAIN GENERALLY.

Mallinckrodt contends it is entitled to partial summary judgment on Plaintiffs' marketing claims as to its generic products because it does not market its generics to physicians. MSJ. Dkt. # 1778-3 at 3-4.[10] But this case is not about a specific product or warning label; and liability does not turn on whether Mallinckrodt promoted its generic opioids specifically to doctors. This case is about the creation of the opioid epidemic, which was spurred in significant part by misrepresentations by Mallinckrodt and other manufacturers about the safety and efficacy of chronic opioid use generally. The record shows that Mallinckrodt engaged in a variety of misleading marketing activities intended

[10] Mallinckrodt makes a brief reference in its motion to the federal labeling scheme for generic drugs and the requirement that generic drug labels must match the FDA approved labeling on their brand-name equivalents. MSJ. Dkt. # 1778-3 at 4. The labeling rules for generic drugs have nothing whatsoever to do with this case. Plaintiffs do not contend that the FDA-approved labeling on Mallinckrodt's generic drugs was misleading, but rather that Mallinckrodt's marketing campaigns to promote both its own drugs and opioid use in general were fraudulent.

to grow the overall market for opioid use and thereby increase sales of all of its opioid products (both branded and generic). Mallinckrodt misrepresented the safety and efficacy of chronic opioid use when promoting its generic opioids to pharmacists and distributors at trade shows and conventions, when distributing "unbranded" materials to physicians and patients, and when promoting branded products to physicians. Plaintiffs seek to hold Mallinckrodt liable for the consequences of this false marketing and have more than sufficient evidence of that misconduct to raise triable issues of fact on their marketing claims.

A. Mallinckrodt promoted its generic opioid drugs to pharmacists, national retail chains, and distributors using materials misrepresenting the safety and efficacy of opioids for chronic pain.

Mallinckrodt frequently promoted its generic products at industry trade shows and conferences. At these shows, besides giving out opioid-themed party favors such as "Oxycodone Krazy Klips," "Oxycodone Puzzle People," or "Morphine ER Computer Mirrors,"[11] Mallinckrodt Generics Sales and Marketing employees would hand out materials misleadingly promoting opioids for chronic pain. For example, Mallinckrodt's Generics sales representatives—NAMs—distributed pain management "pocketcards" regarding the treatment of pain with opioids at trade shows and pharmacy meetings. These pocketcards contained fundamental misrepresentations about the use of opioids, such as the purportedly low risk of addiction, no ceiling dose, treating "breakthrough pain" with more opioids, and using long-acting and short-acting opioids together:

- "Addiction rarely occurs unless there is a [history] of abuse"
- "Most opioid agonists have no analgesic ceiling dose; titrate to relief and assess for adverse effects"
- "With older adults, start dose low, go slow, but go!!"
- "Use long-acting opioids around the clock for baseline management of persistent pain; Use short-acting opioids PRN (rescue) for breakthrough pain"
- "Two drugs of the same class (eg, NSAIDs) should not generally be given concurrently, however long- and short-acting opioids may be prescribed together"

[11] *See, e.g.*, Ex. 7, MNK-T1_0004206740; MNK-T1_0001304097; MNK-T1_0006308768; MNK-T1_0002247620 (combined exhibit of "pre-show worksheets" listing these items among the materials to be distributed).

Ex. 8, MNK-T1_0002183040; *see also* Ex. 9, MNK-T1_0002159713, & Ex. 10, MNK-T1_0001531484. NAMs distributed these misleading pocketcards as part of their standard convention and trade show materials for years.[12]

In addition, Mallinckrodt Generics representatives distributed a brochure titled "Five Steps to Control Chronic Pain"[13] that emphasized the availability of medication as a solution to pain and stated generic drugs like oxycodone and hydrocodone were specifically created to control chronic pain:

> Pharmaceutical solutions are <u>always</u> available to relieve pain. Your physician can choose from several generic and branded drugs specifically created to control chronic pain. These include generic products that contain **oxycodone, hydrocodone, codeine** and related medications.

Ex. 18, MNK-T1_0007040476 (emphasis in original).[14] But drugs like oxycodone and hydrocodone were not created to control chronic pain—on the contrary, they were to be used sparingly for acute pain following trauma or surgery, and later for cancer pain or end-of-life pain.

These trade shows were an important part of Mallinckrodt's promotion of its generic products, and a key tool for reaching a large audience. As a result, Mallinckrodt Generics NAMS attended many such shows each year. The Combined Trade Show Schedule for FY 2010, for example, lists over 130 trade shows handled by the Generics business group. Ex. 20, MNK-T1_0000444963. These meetings

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[12] *See, e.g.*, Ex. 11, MNK-T1_0002699252 (Convention & Trade Show Standard Marketing Material Order as of 1/30/2011 for NAM Steven Becker, listing Pain Management Pocketcard Set, Pk of 10 per 100 Attendees and Oxford American Pocket Cards Breakthrough Pain); Ex. 12, MNK-T1_0000972885 (Standard Marketing Material Order from June 2011 listing Pain Management Pocketcard Set in "Bonnie's Kroger List," "Bonnie's Supervalu List," and "Tim's List"); Ex. 13, MNK-T1_0006632298 (July 14, 2011 email from Senior Sales Coordinator to NAM Bonnie New about shipping Pain Management Pocketcard sets to her for use at MAD Days of Summer Expo, along with morphine brochures, fentanyl lozenge brochures, and fentanyl patch brochures); Ex. 14, MNK-T1_0004841670 (Same list for Harvard Drug Group Trade Partner Expo 2012); Ex. 15, MNK-T1_0004826101-102 (May 28, 2014 Bonnie New email and attachment stating, for the H.D. Smith show, "If the Pain Management Cards become available I need 125"); Ex. 16, MNK-T1_0004862918-919 (July 20, 2015 Lisa Cardetti email and attachment ordering materials for ABC tradeshow including Pain Management Pocketcard Set); Ex. 17, MNK-T1_0005760129-130 (Sept. 29, 2016 Bonnie New email and attachment ordering 250 of the Pain Management Pocketcard Set for the 2016 H.E.B. show); Bonnie New Dep. (02/12/19), Dkt. # 1968-19 at 201:21-203:24.

[13] *See, e.g.*, Ex. 7, MNK-T1_0004206740; MNK-T1_0001304097; MNK-T1_0006308768; MNK-T1_0002247620 ("pre-show worksheets" listing the Chronic Pain brochure among the materials to be distributed).

[14] The marketing materials disseminated at trade shows—in fact, all of Mallinckrodt's marketing materials—were developed on a national basis. As such, there was no difference between the materials used at an Ohio trade show as compared to the marketing materials used at a Florida one. *See* Ex. 19, Kevin Webb 30(b)(6) Dep. (Jan. 17, 2019) at 36:14-37:7.

included national conferences of healthcare professionals such as the American Society of Health-System Pharmacists ("ASHP") Mid-Year Clinical Meeting and the APhA (AmericanPharmacists Association) Annual Meeting, as well as distributor-specific meetings such as the Harvard Drug Vendor Meeting and the Anda, Inc. (now part of Teva Pharmaceuticals) Annual Supply Chain Symposium. *Id.* Thousands of people attended these meetings each year. For example, approximately 7,000 wholesaler buyers were expected to attend the 2005 AmerisourceBergen National Healthcare Conference and Exposition. Ex. 7 at MNK-T1_0004206740. Mallinckrodt's "pre-show worksheet" for the 2004 ASHP Mid-Year Clinical Meeting ("MCM") describes it as "the largest meeting of pharmacists in the world"; "[a]round 10,000 registered pharmacists, thousands of pharmacy students, and a total of 20,000 people attend this meeting each December." Ex. 21, MNK-T1_0001193724. The pre-show worksheet indicates that Mallinckrodt planned to send 16 employees to the meeting, primarily from Generic Marketing, Generic Sales, and Generic Inside Sales. *Id.* Mallinckrodt emphasized the importance of promoting its products to pharmacists, who often make product purchasing decisions:

> Because of our activities and interactions in policies and issues with this audience, we have access to the decision makers that can influence the purchase and use of our products as well as influence the education of pharmacists. Partnership with ASHP will enable us to access pharmacists who make purchasing decisions in a variety of health system settings.

Id. Mallinckrodt also promoted its generic opioids at the annual National Community Pharmacists Association Convention & Trade Exposition, attended by "over 3,000 independent pharmacy leaders, independent pharmacy group purchase organizations, and students." Ex. 22, MNK-T1_0006311200.[15]

The misrepresentation of the safety and efficacy of chronic opioid use to pharmacists was a critical part of the process by which an entire generation of healthcare professionals was duped into

[15] The 2005 National Community Pharmacists Association convention took place in Broward County, Florida, and the theme for the convention that year—"Ride the Independent Wave"—was an ominous one, as the wave of Mallinckrodt oxycodone coming out of Broward County would soon engulf communities in Eastern and Appalachian states, including Ohio.

distributing highly addictive substances and believing it was safe and appropriate to do so. Pharmacist education regarding the safety and efficacy of certain types of drugs is important not only in the context of purchasing decisions with respect to a manufacturers' product and to volume, but also because pharmacists communicate with both physicians and patients, as defense expert Sandra Kinsey explained in her expert report:

> Patients receive verbal and written information from their prescriber and pharmacist that detail precautions and side effects associated with opioid use. . . . Besides dispensing prescriptions, pharmacists are an integral part of the communication process between doctor, manufacturer, insurer, regulatory agencies and patient, ensuring efficacy, safety and access to every drug they dispense for every patient to which they extend care. . . . As part of the prescription filling process, a pharmacist often communicates with prescribers regarding an opioid prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient. Referencing information from a patient's insurance company, national and state opioid databases, or through experience, a pharmacist may refuse to fill a prescription that appears inappropriate based on their professional judgment.

Report of Sandra Kinsey, Dkt. # 1939-17 at 6-7. Mallinckrodt's Generics business also engaged in pharmacist education through Continuing Education courses endorsing opioid treatment for chronic pain, despite the lack of evidence of the effectiveness of chronic opioid therapy and the mounting evidence of serious harms.[16]

B. Mallinckrodt sponsored and distributed misleading "unbranded" promotional materials to encourage the overall prescribing of opioids.

Mallinckrodt, through its "C.A.R.E.S. Alliance" program, funded the distribution of "unbranded" materials promoting opioid use and containing misleading statements about the safety and efficacy of opioids for chronic pain. These materials were provided to both physicians and patients. While not specific to any Mallinckrodt product, generic or branded, they generally promoted

[16] Mallinckrodt Generics offered a Continuing Education course entitled, "Pharmacist Pain Management: A Focus on Opioids and Conversion Issues." Ex. 23, MNK-T1_0004602837; Ex. 24, MNK-T1_0003284656. Mallinckrodt also routinely sponsored an educational program by the American Society of Consultant Pharmacists (ASCP) Foundation for a five-day "Pain Management Traineeship for Pharmacists." Ex. 25, MNK-T1_0000905348 at 350. As another example, Mallinckrodt provided funds to the Johnson County Pharmacy Association in 2005 for a Pain Management Continuing Education Program entitled, "The Pharmacist's Role in Management of Chronic Pain: Focus on Opioids." Ex. 26, MNK-T1_0001308076.

increased opioid prescribing and provided false assurances about ways to prescribe opioids "safely" or "responsibly," even as the opioid epidemic continued to spread and evidence regarding the effectiveness of long-term opioid therapy remained lacking.

Mallinckrodt's C.A.R.E.S. Alliance actively promoted the book *Defeat Chronic Pain Now!*,[17] and Mallinckrodt identified the book as an important "Education and Enabling tool for patients," Ex. 27, MNK-T1_0000098099. Mallinckrodt's catalog of "patient tools"—materials that were made available to prescribers to provide to their patients—described *Defeat Chronic Pain Now!* as providing "patients with ground-breaking strategies for eliminating the pain of arthritis, back and neck conditions, migraines, diabetic neuropathy, and chronic illness." Ex. 28, MNK-T1_0001493093 (C.A.R.E.S. Alliance catalog).[18] This book contains multiple misleading statements promoting opioid use for chronic pain while minimizing the risk of addiction:

- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

Ex. 30, *Defeat Chronic Pain Now!* at pp. 174-177 & Q&A.

[17] CHARLES ARGOFF & BRADLEY S. GALER, DEFEAT CHRONIC PAIN NOW! (Fair Winds Press 2010).

[18] Moreover, Mallinckrodt included *Defeat Chronic Pain Now!* as a "Risk Mitigation Tool" in the Risk Evaluation and Mitigation Strategy (REMS) that it submitted to the FDA in connection with its Exalgo opioid product. Ex. 29, MNK-T1_0000548549.

In addition, Mallinckrodt distributed the book *Responsible Opioid Prescribing: A Physician's Guide*, by Scott Fishman, M.D., through C.A.R.E.S. Alliance. *See* Ex. 31, MNK-T1_0000979208 at 226 ("Q: I heard you can get free Scott Fishman book? A: Yes, it is through our C*A*R*E*S Alliance program, at no cost to you."). The Federation of State Medical Boards contributed to the book which was first published in 2007 with funding from opioid manufacturers, including Purdue, Endo, and Cephalon (now part of Teva). *See, e.g.*, Ex. 32, END00051370.[19] The book contains numerous misrepresentations about chronic opioid therapy, including that long-term opioid use results in improved function and that signs of addiction are "pseudoaddiction." *Id.*

Through C.A.R.E.S. Alliance, Mallinckrodt also created and distributed guides for prescribers and patients that, while not promoting any specific branded or generic product, contained misleading information about opioid use.[20]

C. Mallinckrodt made misrepresentations about opioids generally when promoting branded opioids to doctors, despite its knowledge of the risks from its Addiction Treatment business.

In their promotion of branded opioids to doctors, Mallinckrodt sales representatives made misrepresentations that served to increase physician comfort with prescribing opioids across the board—branded or generic. They used "pocketguides" that contained misleading statements regarding the safety and efficacy of chronic opioid use generally, similar to the "pocketcards" handed out by NAMs at trade shows and pharmacy meetings. In 2008, when promoting Magnacet to doctors, Mallinckrodt sales representatives used a "Pain Pocketguide" about opioids that contained the following false statements:

- Risk of addiction rare
- Single-entity opioids have no maximum dose but may be limited by side effects

[19] SCOTT FISHMAN & FEDERATION OF STATE MEDICAL BOARDS, RESPONSIBLE OPIOID PRESCRIBING: A PHYSICIAN'S GUIDE (Waterford Life Sciences 2007).

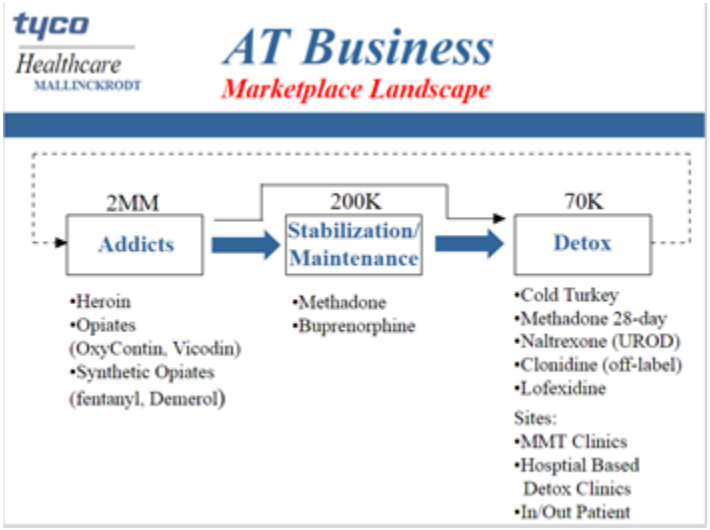
[20] *See, e.g.*, Ex. 33, MNK-T1_0001758643 (C.A.R.E.S. Alliance opioid clinical management guide containing misrepresentations related to pseudoaddiction and the ability to manage withdrawal through tapering); Ex. 34, MNK-T1_0003416495 (C.A.R.E.S. Alliance safe use and handling guide for patients taking opioid pain medicine, containing misrepresentations related to pseudoaddiction and the purportedly low risk of addiction).

- "Pseudoaddiction" = Drug-seeking behavior focused on pain relief, due to undertreatment of pain.

Ex. 35, MNK-T1_0002248919. In 2010, Mallinckrodt appears to have used the same pocketguide when promoting Exalgo, except that by then the guide describe the risk of addiction as "low" rather than "rare." *See, e.g.*, Ex., 36, MNK-T1_0001786865 at 868. These fundamental misrepresentations—that the addiction risk is low, that there is no maximum dose, and that signs of addiction are actually "pseudoaddiction"—are central to Plaintiffs' allegations in this case and are not specific to a particular branded or generic product. Statements such as these contributed to a change in the standard of care that dramatically increased the market for all opioids, which also benefitted Mallinckrodt's generic business.

Mallinckrodt, of course, was uniquely positioned to know the falsity of such statements, given its well-established addiction treatment business. The record shows that Mallinckrodt had long been aware of the highly addictive nature of opioids and how difficult it is to treat opioid addiction. In a 2004 presentation, for example, Mallinckrodt stated that "[o]pioid addiction is a large and growing problem in the U.S." and that "[a]ddiction is a chronic, relapsing brain disorder—a disease." Ex. 37, MNK-T1_0001332076. In its Continuing Education programs, Mallinckrodt taught that "When abused, opioids 'hijack' critical brain functions, leading to continued use of opioids even when the person expresses a desire to stop." Ex. 38, MNK-T1_0006809103. Mallinckrodt also acknowledged that there is no cure for addiction and treatment may be required for a lifetime: "No 'magic bullets.' No 'cure' for addiction. Time required for return to more normal brain function is unknown. Ongoing therapy may be required for a lifetime in recovery." Ex. 39, MNK-T1_0001256480. It noted in a 2001 presentation on the potential market for a detox medication that "Rise in abuse of opioids and OBT [office-based treatment] will increase the number of people in treatment and requiring detox" and that "50% return for second detox (repeat business)." Ex. 40, MNK-T1_0001179053. In a 2002 presentation on its addiction treatment business, Mallinckrodt observed that "OxyContin abuse is

changing the market" and that "[h]eroin users younger than ever before." Ex. 41, MNK-T1_0001179057. In viewing the marketplace landscape for its addiction treatment business, Mallinckrodt saw a perpetual cycle that it could supply throughout—from addiction to stabilization/maintenance to detox and then relapsing back to addiction, as shown by the dotted line in its graphic:



Ex. 42, MNK-T1_0001179054. Mallinckrodt, in other words, was selling on both ends of the addiction cycle. While some Mallinckrodt NAMs were teaching Continuing Education courses on opioids hijacking the brain and that addiction treatment could be required for a lifetime, other NAMs were handing out brochures saying that the risk of addition from chronic opioid use is low and that signs of addiction were "pseudoaddiction" and should be treated with more opioids.

The record in this case demonstrates that Mallinckrodt promoted its opioid products based on fundamental misrepresentations about the safety and efficacy of treating chronic pain with dangerous and addictive narcotics. These misrepresentations were not specific to a particular product and were made in the context of generic product promotion to pharmacists, pharmacy students, distributors, wholesalers, and retail pharmacy buyers as well as unbranded marketing to physicians and patients and promotion of branded products to physicians—all of which increased acceptance of

widespread opioid use and demand for generic opioids. Mallinckrodt's motion for partial summary judgment as to generic marketing should be denied.

II. THE EVIDENCE IS SUFFICIENT TO RAISE A GENUINE ISSUE OF FACT THAT MALLINCKRODT SHIPPED NUMEROUS SUSPICIOUS ORDERS.

Mallinckrodt next argues that Plaintiffs "have failed to identify a single suspicious order that Mallinckrodt purportedly shipped to any of its customers." MSJ. Dkt. # 1778-3 at 5. But the record shows that Mallinckrodt: (a) shipped massive volumes of opioids into Plaintiffs' jurisdictions and neighboring Ohio counties, including to pill mills and problem pharmacies, (b) failed to maintain effective controls against diversion, (c) shipped millions of opioids to wholesalers and downstream customers who were then shut down by the DEA, (d) was aware that opioids shipped to Florida were being trafficked up I-75 to Ohio, Kentucky, and other states, and (e) was aware of problems with abuse and diversion in Ohio yet continued with business as usual. In addition, Plaintiffs' experts' analyses indicate that many of the orders Mallinckrodt shipped should have been flagged and held as suspicious. In short, there is ample evidence for a jury to reasonably find Mallinckrodt liable for its failures to adequately safeguard against diversion.

A. Mallinckrodt supplied large quantities of opioids to the CT1 jurisdictions.

Mallinckrodt contends that it sent only a single, "totally innocuous" order into Summit or Cuyahoga Counties., MSJ. Dkt. # 1778-3 at 6. But Mallinckrodt's opioids dominated the market in Plaintiffs' jurisdictions. Approximately 25% of the morphine-milligram equivalents ("MMEs") sold in Summit and Cuyahoga between 2006 and 2014 were manufactured by Mallinckrodt—more than 2.3 billion (2,363,328,618) MMEs. Report of Craig McCann, Second Supplemental, Dkt. # 2000-16 at 4. Mallinckrodt's "single order" contention is apparently based on consideration only of direct sales to medical facilities, while ignoring its core business of sales through wholesale distributors. MSJ. Dkt. # 1778-3 at 6. But the fact that Mallinckrodt did not directly ship its products to Summit or Cuyahoga pharmacies, and instead provided its opioids to wholesale distributors serving as middlemen, is

irrelevant.[21] Mallinckrodt tracked where its wholesale distributor customers shipped Mallinckrodt opioids with its "chargeback" system—a detailed database of sales by its distributor customers to downstream customers, such as pharmacies and pain clinics. The data included the type of opioid and quantity, as well as the address and DEA registration number of the downstream customer, among other information.[22] Based on this information, Mallinckrodt knew *to the pill* that its opioids were in fact being sold in Summit and Cuyahoga Counties, and that in many cases the downstream customer was what Mallinckrodt's own SOM expert called a "diverter." Ex. 44, Ronald Buzzeo Dep. (06/28/19) at 187:20-188:17 (describing a "diverter" as anyone that diverts controlled substances for illicit purposes including "pain clinics").

In the period covering the years 2003 and 2005 to 2017, Mallinckrodt fulfilled over 58,500 opioid orders that Mallinckrodt itself had identified as "peculiar."[23] Mallinckrodt did not ship those opioids to any distributors in Summit and Cuyahoga Counties—because no distributors are located there. Based on her expertise in data analysis, however, Plaintiffs' expert Lacey Keller used chargeback data to estimate what portion of the orders identified as "peculiar" wound up in Summit and Cuyahoga. In order to make that estimate, she identified Summit and Cuyahoga pharmacies that, within thirty days of a transaction that Mallinckrodt deemed "peculiar," made a repeat purchase of the same opioid product from the same distributor.[24] Ms. Keller determined that of the 58,500 peculiar

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[21] Mallinckrodt certainly did ship opioids to Ohio - many of its large distributors, including Cardinal, KeySource and ANDA, had facilities in the state. *See, e.g.*, Ex. 43, MNK-T1_0000562022 (daily report showing shipped orders to Ohio).

[22] Karen Harper Dep. (01/15/19), Dkt. # 1962-19 at 227:14-18 (describing chargeback data as telling "Mallinckrodt exactly which pharmacy to which the drugs were sold, what the DEA registration number is, the pharmacy address, the quantity, and which drugs they have sold to that pharmacy.")

[23] Keller Rep., Dkt. # 2000-7 at 83-84, *citing* MNK-T1_0008592627 (this exhibit is not attached as it is 6,210 pages long; Plaintiffs will file a copy should there be any dispute about it). Plaintiffs note that, in order to evade the requirements of the CSA, Manufacturers used euphemisms like "peculiar" when their SOM metrics flagged orders of unusual size, frequency, or pattern. *See*, Ex. 106, PPLP004463304 at 7, Purdue Order Monitoring System Presentation ("Outlets with orders outside normal range based on algorithm" referred to as "Potential Problematic Outlets").

[24] Keller chose a 30-day period because (i) many of the SOM algorithms used a 30-day lookback and (ii) chargeback requests were submitted by some distributors on a monthly basis. Lacey Keller Dep. (06/13/19), Dkt. # 1963 13 at 370:9-19.

transactions, 2,860 involved such repeat purchases of the same opioid from the same distributor within 30 days of peculiar transactions. Report of Lacey Keller, Dkt. # 2000-7 at 84.

Ms. Keller also analyzed IQVIA data purchased by Mallinckrodt and other manufacturers and identified eleven specific physicians in Summit and Cuyahoga Counties who violated various compliance metrics. *Id.* at 29-32 & Table 11. For each of the six physician case studies analyzed in detail by Keller in her report, Mallinckrodt was either the top, or among the top, manufacturer (or "labeler") of opioid products prescribed. *Id.* at Tables 13, 15, 17, 19, 21, 24. Mallinckrodt identified these physicians as high-volume prescribers as well—but instead of sharing that information with authorities for anti-diversion efforts, Mallinckrodt designated them as targets for their promotional activities in order to sell more opioids. For example, Mallinckrodt identified Dr. Ronald Celeste of Cleveland as an "oxycodone dominant" high prescriber as early as 2009. *See* Ex. 45, MNK-T1_0002124481. Mallinckrodt listed Dr. Celeste—along with Drs. Guang Yang and Syed Akhtar-Zaidi, who were also identified in Keller's analysis—as a target for Exalgo promotion. These doctors were described as "3 star prescribers," i.e., "prescribers that write a significant number of high dose opioid prescriptions."[25] By December 2013, Celeste had been charged with 226 criminal counts; in the words of the prosecutor's office, he "endangered not only his patients but also the citizens of Cuyahoga County."[26] Despite Mallinckrodt's awareness of Celeste's indictment, it kept him on prescriber lists as a Xartemis target in June 2014.[27] These and other documents indicate that while Mallinckrodt's sales team was aware of problematic opioid prescribers in Ohio, these prescribers were perceived as sales opportunities rather than causes for concern.[28]

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[25] *See, e.g.*, Ex. 46, MNK-T1_0000745147-154 (June 20, 2012 email and attachment).

[26] *See* Ex. 47, MNK-T1_0002134210 (Mallinckrodt employee Jim Young forwarding news update on Dec. 20, 2013); Ex. 48, MNK-T1_ 0005870265 (Jane Williams forwarding news to NAMs on Dec. 20, 2013).

[27] Ex. 49, MNK-T1_0004250514 (referencing Target List for physicians in Cleveland, OH dated June 4, 2014).

[28] *See* Ex. 50, MNK-T1_0007063164 (Email from Ohio District Sales Manager Kevin Becker stating, "It appears that as of November 22, 2011, Dr. Griffin lost his license. He is the districts [sic] 10th largest prescriber and Matt's #2 writer of Exalgo. Crap.").

Mallinckrodt's sales personnel had the ability to direct Mallinckrodt products to specific locales, as demonstrated by the highly dubious shipment of 1500 Oxycodone 15 mg pills per month for a specific individual in Columbus, Ohio, orchestrated by NAM Victor Borelli. This is yet another incident demonstrating Mallinckrodt's cavalier approach to the distribution of narcotics. According to internal Mallinckrodt communications, former Cardinal Health in-house attorney Laura Goodman contacted a Mallinckrodt salesperson directly requesting opioids for her "Aunt Sandra." Ex. 51, MNK-T1_0000562387. Although one Mallinckrodt employee questioned this excessive supply of pills ("I did the math in my head late yesterday and this equates to 50 tablets per day. Is that even possible?"), the Generics sales team at the direction of Borelli arranged for wholesaler customer KeySource Medical to ship the product to Dane Drug, an independent pharmacy in Columbus, Ohio. *Id.* KeySource employee Steve Cochrane wrote to Mallinckrodt NAM Victor Borelli a few days later, exclaiming, "Dane Drug! They wanted to know who the F this lady Aunt Sandra was that showed up looking for her Oxycodone 15mg today! You can't make this stuff up! Dane Drug said they thought it was a crank call when KeySource called Friday to arrange the order with them." Ex. 52, MNK-T1_0000560900.[29]

Mallinckrodt also knew or should have known from its chargeback data about the high volumes of its products going to other problematic prescribers and pharmacies in Cuyahoga and Summit Counties. Ms. Keller's report contains case studies of six such pharmacies. Keller Rep., Dkt. # 2000-7 at 58-82. Keller's analysis shows that the application of various compliance metrics would have flagged each of these pharmacies as suspicious. *Id.* Although Mallinckrodt may or may not have eventually restricted the payment of chargebacks for sales to these pharmacies, *see* Ex. 53, MNK-T1_0001315847, it did not take that measure until 2016, after it had already shipped millions of pills

[29] Mr. Borelli testified that he did not know whether arranging the delivery of opioids to a pharmacy at the request of a colleague was authorized under Mallinckrodt's DEA registration. Victor Borelli Dep. (11/29/18), Dkt. # 1959-7 at 245:12-255:7.

to these pharmacies—12,994,125 total dosage units to these six Summit and Cuyahoga pharmacies between 2006 and 2014 alone, according to ARCOS data.[30] In addition, Mallinckrodt's chargeback data revealed that Dr. Margy Temponeras, despite practicing medicine in a town of only 6,400 people[31], was the highest purchaser of Mallinckrodt 15 mg and 30 mg oxycodone in the entire state of Ohio in the year 2009.[32] Ex. 56, MNK-T1_0000286293. Over a thousand orders of Mallinckrodt product—over 2.5 million pills—went to her through Mallinckrodt customer Miami-Luken.[33] In 2017, Dr. Temponeras pled guilty for her role in operating a pill mill.[34]

In addition to these specific examples, Plaintiffs' expert Craig McCann applied various SOM metrics to Defendants' data and found that, depending on the metric applied, between 26.2% and 90.5% of the Mallinckrodt MMEs shipped in Summit and Cuyahoga Counties were part of suspicious orders. McCann Rep. 2nd Supp., Dkt. # 2000-16 at 9-19.

B. Mallinckrodt was aware that opioids shipped to Florida were being trafficked up the I-75 corridor—the Oxy Express—to Ohio and other states.

Mallinckrodt was also well aware that the opioids flooding Ohio were not limited to those Mallinckrodt shipped directly or through distributors into the state. Opioids shipped to Florida played an outsized role in the opioid-related harms manifesting in Ohio. To illustrate: during the first six months of 2010, Ohio healthcare practitioners prescribed just under a million doses of oxycodone, second only to Florida. But during those same six months, Florida practitioners prescribed ***40.8***

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[30] *See* Keller Rep., Dkt. # 2000-7 at 63-82, Tables 45, 48, 53, 58, 64, 69.

[31] Wheelersburg, Ohio, had a population of 6,437 as of the 2010 Census, Ex. 54 (Apr. 1, 2010).

[32] As Mallinckrodt was well aware, 15 mg and 30 mg oxycodone pills were among the most widely abused and diverted opioids. *See, e.g.*, Steven Becker Dep. (12/19/18), Dkt. # 1956-18 at 339:14-20; *see also* Ex. 55, MNK-T1_0000938024 (Oct. 5, 2016 email from Kevin Webb stating "Oxycodone immediate release (IR) is the most abused opioid on the market, and the most abused product in MNK's portfolio").

[33] Ex. 57, MNK-T1_0007965587-588 (demonstrative summary from large database of Mallinckrodt chargeback data).

[34] Ex. 58, Press Release, U.S. Dep't of Justice, S.D. Ohio (Apr. 7, 2017), *Scioto County Physician Pleads Guilty to Role in Pill Mill*.

million doses—804% more than all other states combined.[35] This extreme oversupply did not remain in Florida, as Mallinckrodt's sales and compliance departments knew.

Mallinckrodt knew of the trafficking of pills from Florida into Ohio and other states along the I-75 corridor, which was such a common occurrence that I-75 was referred to as "the Oxy Express."[36] In a 2012 presentation showing a geographic analysis of cash transactions for oxycodone, the speaker notes describe "[m]any warm and hot spots in FL" and state, "One can also follow the 'oxy express' (highway 75) and see all the cool spots that pop up along the highway known to be used by drug seekers travelling for pills (according to the dea)." Ex. 63, MNK-T1_0002694677. Mallinckrodt also knew from its clients that opioid prescriptions from Florida were appearing in Ohio. *See* Ex. 64, MNK-T1_0000383140 (Aug. 2, 2010 Monthly Report by NAM Bonnie New to supervisor Mike Gunning, reporting on Kroger pharmacy meetings in which Columbus, Ohio, pharmacists said some doctors in the area had been shut down and that "they have prescriptions coming to them from as far as Florida" and "[i]f they fill one then many more follow."). As NAM Steven Becker testified, "Florida became known as an area where all the pain clinics opened up, and it's where people went to get diverted product." S. Becker Dep., Dkt. # 1956-18 at 113:15-17. Becker further testified that he was aware of this issue while still selling oxycodone to his distributor customers, many of whom were directing the majority of their Mallinckrodt purchases into Florida. *Id.* at 114:1-115:4. In 2008, 28% of all of Mallinckrodt's oxycodone 15 and 30 mg pills went to Florida; in 2009 that figure was 39%, and in 2010 it was **47%**. Ex. 65, MNK-T1_0000289707-708.

[35] Ex. 59, Pat Beall, Metro West Daily News (July 8, 2018), *How Florida spread oxy across half of America*.

[36] *See* Ex. 60, John Gillies Dep. (02/08/19) at 40:8-18, 92:23-93:11; Harper Dep., Dkt. # 1962-19 at 91:3-92:19 (acknowledging that the Oxy Express goes from Florida to Ohio). *See also* Ex. 61, MNK-T1_0007185127 (July 9, 2012 Harper email to Gillies forwarding article about "prescription tourists" from Ohio going to Florida for pills); Ex. 62, MNK-T1_0000288998 (Aug. 2011 internal compliance newsletter including information about notorious pain clinic American Pain and stating that "individuals, including addicts and traffickers, seeking to buy large quantities of oxycodone and other controlled substances would travel from as far as Tennessee, Ohio, Kentucky, West Virginia and elsewhere, to obtain prescriptions at the defendants' clinics.").

C. Mallinckrodt failed to maintain effective controls against diversion.

Plaintiffs' CSA -Compliance Brief sets forth the facts demonstrating that Mallinckrodt failed to maintain effective controls against diversion. CSA-Compliance Brief, Dkt. # 1924-1 at 26-35 (Section IIA). Plaintiffs incorporate this section by reference and summarize the highlights here: (a) between 2003 and 2011, Mallinckrodt shipped more than 53 million opioid orders, flagged 37,817 as suspicious and stopped, at most, 33 orders;[37] (b) Mallinckrodt shipped orders *prior* to completing the due diligence on those orders, in direct violation of DEA guidance; (c) Mallinckrodt's SOM program was based upon a rigid numeric formula that its own consultant, Howard Davis, warned was so inadequate that by relying on this formula, Mallinckrodt "would be unnecessarily exposing itself to potential liability;" (d) despite possessing chargeback data as far back as 1998, Mallinckrodt's compliance department did not begin to consider specifically utilizing chargeback data until 2007, and the compliance department did not start evaluating that data until 2009-2010; and (e) Mallinckrodt relied on a conflicted sales force—including a NAM who compared opioid pills to Doritos chips and described his slogan as "ship, ship, ship"—to help determine whether to ship suspicious orders. *See* Plaintiffs' MSJ., Dkt. #1792 at 26-35.

The result was a system so flimsy that Customer Service Representative Brenda Rehkop asked "[c]an we have the PS hold removed for our order flow?? This is the hold the system puts on 'suspicious' orders. We do not do anything with these orders except have to remember to release them." Ex. 79, MNK-T1_0000300799 (May 5, 2011 email to Jim Rausch). The end results were catastrophic—problematic distributors, *who ultimately had their licenses revoked by the DEA*, all received

[37] *See* Mallinckrodt chargeback data produced at MNK-T1_0007965587, MNK-T1_0007965588, and MNK-T1_0008592627; Ex. 66, Mallinckrodt Supp. Resp. to Rog. No. 32 and accompanying Exhibits listing Bates numbers (May 20, 2019); *see also* Ex. 67, MNK-T1_0000274675; Ex. 68, MNK-T1_0000275736; Ex. 69, MNK-T1_0000275748; Ex. 70, MNK-T1_0000259231; Ex. 71, MNK-T1_0000259220; Ex. 72 MNK-T1_0000277496; Ex. 73, MNK-T1_0000475126; Ex. 74, MNK-T1_0007202115; Ex. 75, MNK-T1_0000296226; Ex. 76, MNK-T1_0000269049; Ex. 77, MNK-T1_0000269046; and Ex. 78, MNK-T1_0007026342 (Emails and correspondence regarding specific orders). As noted above, these facts were also presented in Plaintiffs' CSA-Compliance Brief; however, the citations were inadvertently omitted.

substantial amounts of Mallinckrodt products.[38] Mallinckrodt filled over 27,000 opioid orders for these companies, collectively, before the DEA shut each of them down. *See* MNK-T1_0007897646 (Direct Sales Data). Even though chargeback data was available on these problematic distributors, it sat unused. Steven Becker, another highly compensated NAM, repeatedly testified during his deposition that he had access to information on problematic distributors, but never reviewed any of it.[39] This evidence is sufficient for a reasonable jury to conclude that Mallinckrodt's anti-diversion program was lacking—as an effective program would have flagged—and stopped shipment of—many (if not all) of these orders.

D. Mallinckrodt admitted it had a deficient anti-diversion program from 2008 through 2011 in its settlement with the DEA.

According to Mallinckrodt, its SOM program in 2010 was so robust that the St. Louis DEA program manager purportedly told Mallinckrodt that it was an "industry leader" with "the best" process he had ever seen. MSJ., Dkt. # 1778-3 at 7-8. These assertions cannot be squared with the facts. In 2011—the DEA commenced a multi-year investigation into Mallinckrodt's failure to maintain effective controls against diversion.[40] The DEA contended that its investigation revealed numerous deficiencies in Mallinckrodt's nationwide SOM program. *See* Ex. 5, MNK-T1_0000557100 (AMOA). At the conclusion of this investigation, and in lieu of an enforcement action, Mallinckrodt agreed that from January 1, 2008, through January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy

[38] *See* Ex. 80, combined exhibits to the S. Becker Dep., Dkt. # 1956-18: at Ex. 33 (June 15, 2010) (DEA Press Release re Harvard's suspension); at Ex. 35 (Jun. 25, 2014) (DOJ Press Release re Value Drug settlement); at Ex. 36 (Sept. 15, 2015) (DEA Notice of Decision & Order re Masters); at Ex. 37 (Dec. 23, 2016) (DOJ Press Release re civil penalty levied against Cardinal); at Ex. 38 (Jun. 10, 2011) (Press Release re KeySource license suspension).

[39] *See* S. Becker Dep., Dkt. # 1956-18 at 312:11-321:12; 322:16-324:18; 325:1-328:15; 329:8-333:11("Q Okay. And in the chargeback system, at any point in time you could have asked for information on where the product you sold to these entities was shipped --MR. DAVISON: Objection. Q – isn't that right? A I could have, yes. Q And you never once did that? MR. DAVISON: Objection. A I had no reason to on this particular account. Q And you didn't do that for any account, did you? MR. DAVISON: Objection. A Not to my recollection."); 335:1-338:17.

[40] John Gillies 30(b)(6) Dep. (02/07/19), Dkt. # 1962-10 at 239:8-11 (Feb. 7, 2019) (the formal DEA investigation began in September 2011).

Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." *Id.* at 3-4. Putting Mallinckrodt's self-serving characterization of its interactions with the DEA aside, Mallinckrodt has no explanation for the DEA's view, expressed in a PowerPoint presentation, that Mallinckrodt was the "kingpin" of the prescription drug cartel, *see* Ex. 81, MNK-T1_0001807385, nor can it explain the DEA's action against Mallinckrodt for its anti-diversion deficiencies, including deficiencies during the 2010 time period.

III. THE EVIDENCE IS SUFFICIENT TO RAISE A GENUINE ISSUE OF FACT THAT MALLINCKRODT FAILED TO MAINTAIN EFFECTIVE CONTROLS OVER DIVERSION EVEN AFTER 2012.

A. Even after 2012, Mallinckrodt continued releasing "unusual orders" based on representations from sales and marketing and failed to conduct due diligence.

Documents produced by Mallinckrodt indicate that even after 2012, the "due diligence" that Mallinckrodt performed on orders flagged as suspicious continued to be minimal and perfunctory, often requiring only an assurance by the sales representative that the order was not suspicious. Just as it did prior to 2012, Mallinckrodt's compliance department after 2012 released "unusual orders" based on thin representations from the sales personnel who had financial incentives to complete the sales. The following examples illustrate that little changed regarding what passed for "due diligence" after 2012:

- Anda order for morphine sulfate released based on customer's representation of "market disruptions"; customer service representative recommends release despite her concern over month-to-date numbers. Ex. 82, MNK-T1_0001520821 (4/22/13).
- Mallinckrodt released Dakota Drug order for oxycodone before securing necessary forecast from the customer; the December order was 29% of the total YTD amount, indicating a significant increase. Ex. 83, MNK-T1_0008559119 (12/16/13).
- NAM justifies excessive fentanyl order by Rochester Drug Cooperative ("RDC") based on increased sales and moving into NYC metro area. Criminal charges were brought against RDC and its executives in 2019 for conduct covering the time period of this order.[41] Ex. 85, MNK-T1_0004694210 (6/10/14).

[41] Ex. 84, Press Release, U.S. Dep't of Justice, S.D. New York (Apr. 23, 2019), *First Ever Felony Criminal Charges Against a Distributor and its Executives for Illegal Distribution of Controlled Substances*.

- Valley fentanyl order approved based on "increased demand" and the NAM's representations that Valley had a SOM program and was a subsidiary of HD Smith. Both the customer service and compliance departments approved this order, despite the NAM being unable to provide them with basic information about the order, including whether the demand increase was due to one or multiple customers. Ex. 86, MNK-T1_0002265509 (8/28/14).
- Compliance department approved multiple orders on Unusual Order report with no evidence of due diligence. Ex. 87, MNK-T1-0002366293 (9/10/14).
- Burlington order justified based on higher demand created by lower price on 30 mg oxycodone (one of Mallinckrodt's most abused products). Customer service representative approves the order even though Burlington did not provide the updated forecast that had been requested by the Mallinckrodt compliance department. Ex. 88, MNK-T1_0002365784 (5/26/15).
- RDC order for 30 mg oxycodone approved after the Mallinckrodt product manager created a justification for the increased order (based on price change and other suppliers' delays) and provided that justification to the customer. RDC promptly parroted this justification for the increased order back to the Mallinckrodt compliance department. Ex. 89, MNK-T1_0008520222 (8/18/15).
- Orders for hydromorphone and methadone released for McKesson, based on McKesson's unsupported representation that there was a "spike in the last couple of weeks." Ex. 90, MNK-T1_0005975029 (3/24/16).
- McKesson order for 15 mg oxycodone released despite the fact that monthly order exceeded the threshold limit (110% of the previous month's order) by almost 600 bottles. The order was released before receiving the necessary McKesson forecast "for the SOM files." Ex. 91, MNK-T1_0007187021 (7/25/16).

B. Even after 2012, Mallinckrodt continued to stop a *de minimis* number of suspicious orders.

The above examples are indicative of a larger pattern: Mallinckrodt's inability, or unwillingness, to stop suspicious orders. Mallinckrodt's monthly unusual order reports demonstrate that the usual pattern was for hundreds of such "unusual orders" to be released and none were withheld. *See, e.g.*, Ex. 92, MNK-T1_0001520988 (all 600-plus unusual orders in January 2014 were released); Ex. 93, MNK-T1_0001810743 (all 700-plus unusual orders in September 2014 were released).

In fact, post-2012, the number of orders Mallinckrodt flagged as potentially suspicious or held from shipment, as compared to the total volume of orders it filled, remained essentially the same as what had occurred under Mallinckrodt's previous, admittedly deficient, anti-diversion program. Based on the data Mallinckrodt provided, Mallinckrodt processed approximately 35 million orders between 2012 and 2016, inclusive. *See* MNK-T1_0007965587 & MNK-T1_0007965588 (chargeback data indicating 35,242,337 total orders). During that time period, Mallinckrodt identified 26,911 orders as

potentially suspicious. However, the number of orders actually reported to the DEA and cancelled from shipping remained minimal. From 2012 to 2016, Mallinckrodt reported to the DEA and stopped shipment on only 143 orders out over 26,000 suspicious orders (and over 35 million total orders). *See* Ex. 3, MNK Rog Resp. No. 32, Exs. 4 & 5; *see also* Suspicious Order Report produced at MNK-T1_0008593009.

C. After 2012, Mallinckrodt also continued to ship significant volumes of opioids to distributors that were violating the law.

One of the significant failures of Mallinckrodt's SOM program was its repeated shipments of opioids products to wholesale distributors up until the distributors had their licenses revoked by the DEA. Even after 2012, Mallinckrodt continued to ship to problematic distributors, including Miami-Luken and the RDC. According to Mallinckrodt's direct sales data, between 2012 and 2017, Mallinckrodt sold over $4.6 million worth of opioids to Miami-Luken. *See* MNK-T1_0007897646 (Direct Sales Data). According to Mallinckrodt's chargeback data, during this time period Miami-Luken shipped over 21,555 orders of Mallinckrodt products to pharmacies and other end users, with many of these orders—13,697 orders—ultimately *shipped into Ohio*. *See* MNK-T1_0007965587 & MNK-T1_0007965588 (chargeback data). In fact, out of the 72,268 orders shipped between 1998 and 2017, 65% (46,987 orders) went to Ohio. *Id.* Between 2012 and 2017, Mallinckrodt sold over $42 million worth of opioids to the RDC. *See* MNK-T1_0007897646 (Direct Sales Data). According to chargeback data, during this time period Miami-Luken shipped over 120,000 orders of Mallinckrodt products to pharmacies and end users, with 4,659 of these orders shipped into Ohio. *See* MNK-T1_0007965587 & MNK-T1_0007965588 (chargeback data).

Both RDC and Miami-Luken have been criminally charged by the DOJ, including for conduct after 2012. According to DOJ, "[f]rom 2012 through March 2017, as alleged, RDC knowingly and intentionally violated the federal narcotics laws by distributing dangerous, highly addictive opioids to pharmacy customers that it knew were being sold and used illicitly." Ex. 84, Press Release (Apr. 23,

2019). In addition, during this time, "RDC took steps to conceal its illicit distribution of controlled substances from the DEA and other law enforcement authorities. Among other things, RDC made the deliberate decision not to investigate, monitor, or report to the DEA pharmacy customers that it knew were diverting controlled substances for illegitimate use." *Id.* A federal grand jury has charged Miami-Luken, its former president and former compliance officer, and two pharmacists with conspiring to distribute controlled substances.[42] According to the DEA, Miami-Luken supplied pharmaceuticals to more than 200 pharmacies in Ohio, West Virginia, Indiana, and Tennessee. *Id.* The DEA alleges that Miami-Luken ignored "obvious signs" of abuse by, for example, distributing more than 2.3 million oxycodone pills and 2.6 million hydrocodone pills to Westside Pharmacy in Oceana, West Virginia, a town of approximately 1,394 people. *Id.* In addition, from 2008 through 2014, Miami-Luken distributed more than 6 million hydrocodone pills—and 120,000 painkiller pills in one month—to Tug Valley Pharmacy, in Williamson, West Virginia, a town of approximately 2,800 people. *Id.* From 2012 through 2014, Miami-Luken provided another 2.2 million pills to another pharmacy that had been cut-off from other wholesalers. *Id.* These indictments indicate that even after 2012, Mallinckrodt was continuing to provide its opioid products to distributors that were supplying vast amounts of opioids to pill mills.

Mallinckrodt's chargeback data indicates that Tug Valley Pharmacy received Mallinckrodt opioid products from at least five distributors in addition to Miami-Luken, including KeySource, Masters, AmerisourceBergen, Harvard Drug, and H.D. Smith, between 2007 and 2010. *See* Ex. 95, MNK-T1_0000582548. A pharmacy obtaining opioids from multiple distributors should have been a red flag for diversion, and KeySource and Harvard Drug both later had their licenses revoked by the DEA. Moreover, Mallinckrodt knew in 2010 that H.D. Smith had cut off Tug Valley because of suspicious orders. *See* Ex. 96, MNK-T1_0000560461-464 (Aug. 7, 2010 email exchange between NAM

[42] Ex. 94, Press Release, Drug Enf't Admin., (July 18, 2019), *Pharmaceutical distributor and executives, pharmacists charged with unlawfully distributing painkillers.*

Victor Borelli and Product Manager Kate Muhlenkamp regarding the list of pharmacies identified by H.D. Smith as suspicious and attached list). Mallinckrodt, however, continued shipping opioids to Tug Valley through other customers well past 2012. *See* Ex. 97, MNK-T1_0000582548 (chargeback report run by Mallinckrodt on Tug Valley transactions showing significant purchases from Miami-Luken and McKesson post-2012). Despite all of these red flags, Mallinckrodt did not place Tug Valley on its "chargeback restriction" list until January 2016. Ex. 98, MNK-T1_0001384980.

Another notorious pill mill, and customer of Miami-Luken and Mallinckrodt, was Colony Drug in Beckley, West Virginia, thirty-five miles from Oceana.[43] Colony Drug became the subject of Congressional scrutiny as a result of the U.S. House Committee on Energy and Commerce's investigation of "pill dumping" by drug wholesalers, particularly Miami-Luken and H.D. Smith.[44] The Congressional committee found that Miami-Luken sent more than 7 million hydrocodone and oxycodone pills over an 11-year period to Colony Drug, and the number of oxycodone pills doubled from 570,400 in 2010 to 1,151,600 in 2013.[45] Mallinckrodt chargeback reports also identified large, rapidly increasing sales to Colony Drug in 2009 and 2010[46]; and in 2010, Mallinckrodt first red-flagged Colony for sourcing oxycodone from multiple distributors. *See* Ex. 103, MNK-T1_000501797; Ex. 104, MNK-T1_000501796. Nevertheless, Mallinckrodt's opioids continued to go to Colony through multiple distributors for the *next three and a half years*, a distribution pattern that was readily apparent from Mallinckrodt's chargeback data.[47] The examples of Tug Valley and Colony Drug are significant

[43] In addition to receiving large amounts of Mallinckrodt opioids through multiple distributors, Colony Drug also directly purchased opioids from Mallinckrodt. Between 2011 and 2013, Mallinckrodt *directly* sold $21,100 of bulk opioid powders to Colony Drug. Ex. 99, MNK-T1_0001369672.

[44] Ex. 100, Courtney Hessler, The Herald-Dispatch (Feb. 4, 2018), *Answers sought on delivery of pills.*

[45] *Id.*

[46] Ex. 101, MNK-T1_0000292981 (report for 2009 oxycodone sales, run 8/31/11, indicating Colony purchased over 131,000 MNK oxy 15 and 30 pills from three distributors); Ex. 102, MNK-T1_0000286297 (similar report for 2010, run 8/31/11, showing Colony purchases of over 294,000 oxycodone pills, including 281,900 from Miami-Luken).

[47] Ex. 99, MNK-T1_0001369672 (2014 chargeback report showing significant sales of Mallinckrodt products through multiple distributors from 2010-2014).

in that they demonstrate the deficiencies in Mallinckrodt's "chargeback review," a key component of Mallinckrodt's purportedly "robust anti-diversion program." MSJ. Dkt. # 1778-3 at 7. These examples highlight a consistent problem with Mallinckrodt's SOM program: a failure of implementation. Both before and after 2012, Mallinckrodt's chargeback data revealed problematic pharmacies receiving Mallinckrodt opioids, but Mallinckrodt failed to act on this information.

D. Mallinckrodt cannot establish with undisputed facts that its 2012 anti-diversion program was any more effective than its prior programs.

Mallinckrodt makes much of the fact that Plaintiffs' expert, Dr. Seth Whitelaw, declined to express an opinion regarding its post-2012 anti-diversion program. This is largely a consequence of Mallinckrodt's document production, which is heavily weighted towards pre-2012 documents. Indeed, as Mallinckrodt's own deposition exhibit makes clear, Dr. Whitelaw's report is primarily based on documents from the 2007-2012 time-period. *See* Ex. 105, Whitelaw Dep. Ex. 23 (indicating that out of the 145 documents cited by Dr. Whitelaw in his report, only nine of those documents post-date 2012). But the skewed nature of Mallinckrodt's document production does not mean that Plaintiffs "have developed no evidence that Mallinckrodt's anti-diversion program was deficient after 2012." MSJ. Dkt. # 1778-3 at 1. To the contrary, as explained above, Plaintiffs have developed abundant evidence that Mallinckrodt's post-2012 anti-diversion program suffered from many of the same deficiencies as its pre-2012 program.

Mallinckrodt has failed to come forward with facts, let alone undisputed facts, establishing that its 2012 anti-diversion program was any more effective than its prior programs. While Mallinckrodt emphasizes its "voluntary chargeback review and reporting of downstream registrants" (MSJ. Dkt. # 1778-3 at 7), Mallinckrodt concedes that these measures were in place in early 2010. As discussed above, the DEA alleged, and Mallinckrodt agreed, that from January 2008 through January 2012—notwithstanding these measures—"certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards" outlined by the DEA in its 2006 and 2007

guidance letters. Ex. 5, MNK-T1_0000557100 (AMOA) at 3-4. Moreover, there is nothing in the record indicating that Mallinckrodt undertook any type of systematic review of its anti-diversion programs to evaluate whether its post-2012 programs were in fact superior to its pre-2012 programs. In this instance, what's past is prologue—the same deficiencies that were found in the pre-2012 anti-diversion program remain in the post-2012 time period. Mallinckrodt is still continuing to ship suspicious orders based on flimsy justifications; Mallinckrodt is still only halting and reporting to DEA a *de minimis* number of suspicious orders (143 out of over 26,000 flagged orders); and Mallinckrodt opioid products continued to be shipped to problematic end users. Given this, Mallinckrodt is not entitled to partial summary judgment that Plaintiffs' diversion claims end in 2012.

CONCLUSION

Mallinckrodt's motion for partial summary judgment should be denied.

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Respectfully submitted,

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